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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,275	03/01/2004	Glade Harold Howell	P-5401C1	9525

26253 7590 10/04/2006

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EXAMINER
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BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/790,275

Applicant(s)

HOWELL ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 6, 8-10, 12, 14-16, 19, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Luther et al (US 2003/0153873). Luther discloses an over the needle intravenous catheter comprising a tube 12 made of flexible, biocompatible material having a lumen substantially co-axial with the tube (paragraph 0015), the lumen having a proximal cross section larger than the distal cross section. See Fig. 1. The tube further comprises a shoulder 30, and a land portion disposed between the shoulder and the distal end of the tube, the land having a predetermined length (paragraph 0019). See Fig. 1. Luther discloses a needle 14 having a substantially circular cross section and a needle tip, the needle disposed in the lumen, the needle further comprising a discontinuity 32 having a distal edge, wherein the distance between the distal edge of the discontinuity and the needle tip is greater than the length of the catheter land, and the discontinuity is sized such that it fits within the lumen at the proximal portion but not at the distal portion (paragraph 0019). See Fig. 1. Regarding claim 6, the shoulder is shaped to match the distal edge of the continuity. See Fig. 1. Regarding claim 8, the needle is disposed slidably within the lumen (paragraph 0004). Regarding claim 10, the distal portion of the outer wall of the tube is tapered toward the opening in the catheter tip. See Fig. 1. Regarding claims

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12 and 19, the shoulder is disposed at an angle of about 90 degrees. See Fig. 1. Regarding claim 20, Luther discloses that the shoulder includes a ridge 30.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Koehn (US 3030953). Claim 2 differs from Luther in calling for the cross section of the needle to be larger than the distal cross section of the lumen. Koehn teaches an over the needle catheter comprising a needle having a larger outside diameter than the inside diameter of the catheter tube to provide a guide for the end of the tube so that the catheter can enter the tissue without catching or tearing the tissue (Col. 4, lines 10-15, 30-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Luther such that the cross section of the needle is larger than the distal cross section of the lumen as taught by Koehn to provide a guide for the end of the tube so that the catheter can enter the tissue without catching or tearing the tissue.

5. Claim 5 differs from Luther in calling for the needle to include a notch. Koehn teaches that the needle includes a groove 21 on the periphery of the needle so that blood can be observed as it flows into the catheter through the groove (Col. 6, lines 19-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of

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Luther to have a notch as taught by Koehn so that that blood can be observed as it flows into the catheter through the notch.

6. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Leschinsky et al (US 6179825). Claims 3 and 17 differ from Luther in calling for the catheter to have an oval cross section. Leschinsky teaches a catheter having an oval cross section that is able to be inserted into the vasculature with minimal obstruction to blood flow (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the catheter of Luther to have an oval cross section as taught by Leschinsky so that the catheter is able to be inserted into the vasculature with minimal obstruction to blood flow.

7. Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther in view of Raulerson (US 5599311). Claims 4 and 18 differ from Luther in calling for the catheter to have ribs that engage the needle. Raulerson teaches a cuff 10 that has one or more ribs 56 on the interior surface to engage a catheter inserted there through (Col. 10, lines 13-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Luther to have ribs on the internal surface of the catheter as taught by Raulerson to engage and maintain the needle.

8. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther. Claims 11 and 13 differ from Luther in calling for the shoulder to be disposed at an angle of 45

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or 86 degrees. At the time the invention was made, it would have been an obvious matter of design choice to make the angle of the shoulder 45 or 86 degrees. Applicant has not disclosed that having the shoulder at those particular angles serves and advantage of particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Luther's catheter and applicant's invention to perform equally well with a 45, 86 or 90 degree angle of the shoulder. Therefore, it would have been prima facie obvious to modify Luther to obtain the invention as specified in claims 11 and 13 because such a modification would have been considered a mere design consideration which fails to patentable distinguish over the prior art of Luther.

### ***Response to Arguments***

9. Applicant's arguments filed 7/7/06 have been fully considered but they are not persuasive. Applicant asserts that the Luther reference does not teach that the catheter land has a predetermined length and cross section such that a needle tip can be completely enveloped in the catheter tip. As the Luther reference shows, the needle tip can easily slide distally and be entirely contained within the catheter.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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